

Notice of Allowability

Application No.

10/523,184

Examiner

Yong Chu

Applicant(s)

MERTENS, JOHN J.R.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 8/24/2006.
2. ☒ The allowed claim(s) is/are 1,3,5,6,9-11 and 27-29.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☒ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

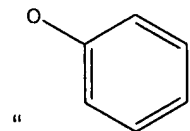
DETAILED ACTION

Amendment filed on 24 August 2006 has been entered. Claims 2, 4, 7-8, and 12-24 have been canceled by the Amendment filed on 24 August 2006. Claims 25-29 have been added the Amendment filed on 24 August 2006. Claims 1 and 3 have been amended by the Amendment filed on 24 August 2006. Therefore, Claims 1, 3, 5-6, 9-11, and 25-29 are pending in this application.

Response to Amendment

A telephonic interview was conducted with Applicants' representative Kathleen M. Petrillo on 18 August 2006, 30 August 2006, and 31 August 2006 to discuss the Final Rejection on the claims. The Supplementary Amendment by Applicants' representative Kathleen M. Petrillo dated on 24 August 2006 has been considered and partially entered.

The rejection over claim 1 under 35 U.S.C. §102(b) has been withdrawn due to the Amendment filed on 24 August 2006. The amendment adds "and the X-(CH₂)_n- is a side chain on the ring" in claim 1 to further limit the way how the side-chain is attached to "R". The amended claim 1 excludes the rejection based on the prior art wherein R as



The rejection over claims 1, 3, 5-6, and 9-11 under 35 U.S.C. §103(a) have been withdrawn due to the Examiner's Amendment. The amendments adds "R is phenyl having the X-(CH₂)_n- as a side chain" in claim 1 and 3 to overcome the 103(a) rejection.

The rejection over claim 1 under 35 U.S.C. §112 2nd paragraph has been withdrawn due to the Amendment filed on 24 August 2006. The amendment adds "and the X-(CH₂)_n- is a side chain on the ring" in claim 1 to further clarify how the side-chain is attached to "R". Therefore, the rejection is withdrawn.

Examiner's amendment

An examiner's amendment to the record appears below with the authorization from Applicants' representative Kathleen M. Petrillo dated on 31 August 2006. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

In Claim 1 of the Amendment dated on 24 August 2006, line 1, delete "analogue having the general" after "A halogenated amino acid" and insert --compound of --.

In Claim 3 of the Amendment dated on 24 August 2006, line 1, delete "analogue having the general" after "A halogenated amino acid" and insert --compound of --.

In Claim 3 of the Amendment dated on 24 August 2006, line 9, insert --having the X-(CH₂)_n- as a side chain-- after "R is phenyl".

In Claim 5 of the Amendment dated on 24 August 2006, line 1, delete "analogue" after "5. (Previously amended) The " and insert --compound--.

In Claim 6 of the Amendment dated on 24 August 2006, line 1, delete "analogue" after "6. (Previously amended) The " and insert --compound--.

In Claim 9 of the Amendment dated on 24 August 2006, line 1, delete "analogue" after "9. (Original) The " and insert --compound--.

In Claim 9 of the Amendment dated on 24 August 2006, line 12-14 on page 4, delete " ; [¹⁸F] labeled alanine; [¹⁸F] labeled valine; [¹⁸F] labeled leucine; [¹⁸F] labeled isoleucine; and [¹⁸F] labeled methionine" after "3-(4-fluoroethyl-6-hydroxy-pyridine-2-yl)-propionic acid".

In Claim 10 of the Amendment dated on 24 August 2006, line 2, delete "analogue" after "the " and insert --compound--.

In Claim 27 of the Amendment dated on 24 August 2006, line 1, delete "analogue" after "A method for preparing the" and insert --compound--.

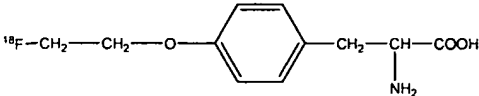
Delete Claims 25-26.

Reasons for Allowance

The present invention relates to a radioactive halogenated amino acid analogue

of Formula
$$\begin{array}{c} \text{X-(CH}_2\text{)}_n\text{-R(CH}_2\text{)}_m\text{-CH-COOH} \\ | \\ \text{NH}_2 \end{array}$$
, a pharmaceutical composition containing at least one of the said compounds, a method for preparing the analogue and a method for using the analogue for diagnosing a patient for the presence of tumors. The closest prior art of record is by Wester et al., Journal of Nuclear Medicine, 1999, 40(1), 205-212. Wester et al. disclose a specific compound of O-(2-[¹⁸F] fluoroethyl-L-Tyrosine claiming a

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compound of formula  for the same application. The

amendments supra have overcome the rejections under 102(b) and 103(a). Therefore, the rejections have been withdrawn.

The method of preparation of the claimed compounds is enabling by the disclosure in the Specification.

Conclusion

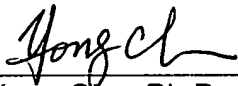
Claims 1, 3, 5-6, 9-11, and 27-29 are allowed.

Telephone Inquiry

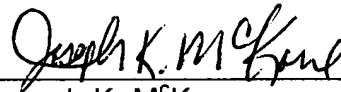
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached on 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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